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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/644,150 | 08/20/2003 | Jean-Marie Stutzmann | USST98048USDIV | 6499 |

5487 7590 08/11/2004

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| EXAMINER | |
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| ART UNIT | PAPER NUMBER |
|---|---|
| 1623 | |

DATE MAILED: 08/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/644,150 | STUTZMANN ET AL. | |
| | Examiner | Art Unit | |
| | EVERETT WHITE | 1623 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1-19 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-19 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Claim Objections*

1. Claim 8 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 8 recites how the low molecular weight heparin is obtained. The recitation is not further limiting. It does not matter how the heparin is obtained.

### *Double Patenting*

2. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

3. Claims 1-19 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of Claims 1-19 of copending Application No. 10/644,109. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

### *Claim Rejections - 35 USC § 112*

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. **Claims 1-19** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In **Claim 1**, the metes and bounds of the term "exposing" cannot be determined, which renders the claims indefinite. The phrase "exposing the motoneurons to a low molecular weight heparin" should be replace with a more definite phrase such as - - contacting the motoneurons with a low molecular weight heparin - -.

**Claims 18 and 20** recite alphanumeric notations for the heparins. It is not clear what these notations mean. Perusal of the specification failed to clarify these alphanumeric notations. The notations should be replaced with a chemical name or structure.

Claims depending from Claim 1 (see **Claims 2-19**) are also rejected since these claims do not clarify the indefinite language used in Claim 1.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claim 2 is rejected under 35 U.S.C. 102(b) as being anticipated by VonArnim (WO 94/18988).

Applicants claim a method for treating a motoneuron disease in a patient in need thereof comprising administering to the patient a pharmaceutically effective amount of a low molecular weight heparin.

The VonArnim patent discloses treatment of multiple sclerosis by administering to a patient a pharmaceutical composition comprising heparin (see the abstract and the 1st paragraph of page 1), which anticipates the instantly claimed invention of treating a motoneuron disease since multiple sclerosis is within the scope of motoneuron diseases.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 1 and 4-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Snow et al (WO 91/06303).

Claim 1 is drawn to a method for increasing the survival or growth of moto-neurons comprising exposing the motoneurons to a low molecular weight heparin. Additional limitations in the dependent claims include specifying the molecular weight of the low molecular weight heparin and specifying specific types of low molecular weight heparin.

The Snow et al patent teaches the use of glycosaminoglycans that may be selected as heparin and molecules and compositions comprising glycosaminoglycans such as heparin to promote nerve regeneration or nerve growth (see abstract), which is within the scope of the instantly claimed method of increasing the survival or growth of motoneurons. The instant claims differ from the Snow et al patent by specifying the molecular weight of heparin. However, ranges of molecular weight cannot be the basis for patentability of subject matter encompassed by the prior art where there is nothing to indicate such range is critical. *In re Hoeschele* (CCPA 1969) 406 F2d 1403, 160 USPQ 809; *In re Cole* (CCPA 1964) 326 F2d 769, 140 USPQ 230. It appears that Applicants only set forth in the claims the use of a heparin compound of lower molecular weight in a method for which the heparin is already known for in the art. One having ordinary skill in the art would have been motivated to employ the method of the prior art with the expectation of obtaining the desired outcome because the skilled artisan would have expected the closely related heparin compounds to react similarly.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of Applicants invention to replace the heparin used to promote nerve regeneration or nerve growth of the Snow et al patent with a heparin compound of lower molecular weight in view of their closely related structures and the resulting expectation of similar regenerative properties.

10. Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Snow et al (WO 91/06303).

Applicants claim a method for treating a motoneuron disease in a patient in need thereof comprising administering to the patient a pharmaceutically effective amount of a low molecular weight heparin. Additional limitation in the dependent claim includes specific types of motoneuron diseases.

The Snow et al patent teaches the use of glycosaminoglycans that may be selected as heparin and molecules and compositions comprising glycosaminoglycans such as heparin to promote nerve regeneration or nerve growth (see abstract). See page 32, line 29 to page 33, line 29, wherein Snow et al describes growth-promoting

compositions which can be administered to patients to treat various types of disorders, including motoneuron diseases such as amyotrophic lateral sclerosis (see page 33, line 9), which is one of the motoneuron diseases set forth in instant Claim 3. The instant claims differ from the Snow et al patent by specifying the molecular weight of heparin. However, ranges of molecular weight cannot be the basis for patentability of subject matter encompassed by the prior art where there is nothing to indicate such range is critical. *In re Hoeschele* (CCPA 1969) 406 F2d 1403, 160 USPQ 809; *In re Cole* (CCPA 1964) 326 F2d 769, 140 USPQ 230. It appears that Applicants only set forth in the claims the use of a heparin compound of lower molecular weight in a method for which the heparin is already known for in the art. One having ordinary skill in the art would have been motivated to employ the method of the prior art with the expectation of obtaining the desired outcome because the skilled artisan would have expected the closely related heparin compounds to react similarly.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of Applicants invention to replace the heparin used to treat motoneuron diseases such as amyotorphic lateral sclerosis of the Snow et al patent with a heparin compound of lower molecular weight in view of their closely related structures and the resulting expectation of similar therapeutic properties.

***Summary***

11. All the claims are rejected.

***Examiner's Telephone Number, Fax Number, and Other Information***

12. For 24 hour access to patent application information 7 days per week, or for filing applications, please visit out website at **www.uspto.gov** and click on the button "Patent Electronic Business Center" for more information.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is (571) 272-0660. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reach on (571) 272-0661. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

E.White

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